Johns Hopkins Investigating Clinical Trial in India

Patients Allegedly Were Not Fully Informed of Risks of Cancer Drug Used in Researcher's Study

By Shankar Vedantam
Washington Post Staff Writer
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Johns Hopkins University has launched an investigation into a clinical trial conducted in India by a faculty member following allegations that patients were not fully informed of the risks.

The university said it discovered in March that the experiment had not been approved by a university oversight committee but had not thought it was necessary to launch an investigation until two weeks ago, when reports of irregularities in the conduct of the trial surfaced in the Indian media.

The investigation comes in the wake of major problems with the Baltimore university's massive research enterprise.

In recent weeks, after the death of a young woman in an asthma study, federal watchdogs have clamped harsh controls over the 2,800 federally funded clinical trials being conducted at the university and demanded that school officials review each to make sure they were approved according to proper procedures.

Although school officials declined to identify the researcher involved in the Indian trial, Ru Chih Huang, a professor of biology at the university, acknowledged yesterday in a telephone interview that she had helped to conduct a trial in the southern Indian state of Kerala and tested a cancer medicine on 25 patients with oral cancer during 1999-2000.

Huang, who said she had been limited by the university about how much she could say about the case, denied that the drug was toxic. On the contrary, she said, the medicine had done exceedingly well during the trial and no patients had reported any toxicity.

"I can only say that I have done good to the people of India by using this drug because it doesn't bring toxicity to humans, but it achieves the effect," she said. "It works absolutely beautifully."

Hopkins officials said they could not comment on the Indian allegations until the investigation was complete. Provost Steven Knapp, the university's senior vice president for academic affairs, said a three-person committee had been established, in accordance with the school's procedures, to investigate.

"There is no question of whether any improvements are needed in our internal processes because this never went through our internal processes," he said. Despite the flap over the current experiment as well as the death of the asthma patient, Knapp said, "it would be unfair to conclude that research in general at Hopkins is flawed. Given the volume of research that goes on at Hopkins, one can't generalize."

In a letter obtained by The Washington Post, Hopkins told the federal Office for Human Research Protections (OHRP) on Friday that a committee would investigate whether the Indian trial had received FDA approval for the export of a drug and whether the researcher had spoken for the university without authorization, and would find out who had funded the project.

Bill Hall, a spokesman for the Department of Health and Human Services, said the OHRP would be involved in the investigation only if federal funds were used in the experiment.

Knapp said he believed no federal funds were used.

Reports in Indian newspapers and wire services said a radiologist at a cancer center in the southern state of Kerala had filed a complaint with a human rights organization charging that the medicine used in the trial – tetramethyl NDGA – was toxic and had been banned from use in the United States.

In addition, according to the reports, the radiologist, V.N. Bhattathiri of the Regional Cancer Center, alleged that the experimental treatment was given to patients who could have benefited from conventional treatment.

The reports said the trial had been approved by the Indian government.

Huang said that although NDGA could be toxic, the tetramethyl form of the chemical was safe because it reduced the chemical's ability to travel within the body.

When physicians inject the drug directly into solid tumors in the breast or brain, it can kill cancer cells without damaging healthy tissue, she said.

"Why did I have to go to Trivandrum to do this?" Huang said, referring to an Indian city. "It is because 80 percent of oral cancer is there. Do you know what [patients] die of? Hunger. The disfiguration is terrible. The drug can be made fairly cheap – I feel very sad that the country will not see the good side of it."

Patients who had already been scheduled to have their tumors surgically removed were administered two to three days worth of the medicine, she said. After the tumors were removed, she said, chemical analysis of the tumor had shown that the medicine had killed cancer cells.

Hopkins and Huang said a proposal to conduct a more comprehensive trial that could take the medicine beyond the proof of concept stage was being evaluated by the university's Institutional Review Board.